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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,508	04/27/2001	Alan P. Wolffe	8325-0014	9058
23419	7590	10/20/2003	EXAMINER	
COOLEY GODWARD, LLP 3000 EL CAMINO REAL 5 PALO ALTO SQUARE PALO ALTO, CA 94306			SANDALS, WILLIAM O	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/844,508

Applicant(s)

WOLFFE ET AL.

Examiner

William Sandals

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attached.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-6, 8, 10-13, 17-33 and 43-70.

Claim(s) withdrawn from consideration: 7, 9, 14-16, 34-42, 71, 72.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

DETAILED ACTION

Status of the Claims

The after final amendment to the claims filed August 21, 2003 will not be entered because it does not simplify the issues. The amendment also would require new grounds of rejection of claims 10 and 68 under 35 USC 112, second paragraph, and claims 1-6, 8, 10-13, 17-33 and 43-70 under 35 USC 102 and 103.

Claims 1-72 are pending. Claims 7, 9, 14-16, 34-42, 71 and 72 stand withdrawn from consideration.

Claims 1-6, 8, 10-13, 17-33 and 43-70 stand provisionally rejected under the judicially created doctrine of Obviousness Double Patenting over claims 1-15 and 17-20 in copending Application No. 09/942,087.

Claims 1-6, 8, 10-13, 17-33 and 43-70 stand rejected under 35 USC 112, first paragraph, written description.

Claims 1-6, 8, 10-13, 17-33 and 43-70 stand rejected under 35 USC 112, second paragraph.

Claims 1-5, 8, 10, 12, 13, 17, 18 and 68-70 stand rejected under 35 USC 102 as being anticipated by US 6,183,965 (Verdine et al.).

Claims 1-6, 8, 10-13, 17-33 and 43-70 stand rejected under 35 USC 103 as obvious over US 6,183,965 (Verdine et al.) in view of US 5,972,608 (Peterson et al.), and further in view of Cardoso et al., Omichinski et al. and Rutter et al.

Response to Arguments

Arguments presented in the amendment after final filed on August 21, 2003 at page 9, request a withdrawal of finality, asserting that the newly presented rejections in the final office action mailed July 2, 2003, were not necessitated by applicant's previous amendments. It is asserted that the same references were applied in the non-final rejection mailed March 11, 2003, and that there is no reason why the newly made rejection in the final rejection could not have been made in the non-final rejection.

This argument is not found persuasive. The amendment to the claims in the paper filed April 18, 2003, response to the non-final rejection, overcame the rejection of the claims under 35 USC 102(e) over Case and over Bestor, and the rejection of the claims under 35 USC 103 over Case and Bestor in view of Natesan and Verdine, and thus, necessitated the new grounds of rejection. In the newly made rejections, new art is cited, and new grounds of rejection are set forth to address the amendments to the claims. The final rejection was necessitated by amendment, and the new grounds of rejection addressed the amendment to the claims.

Arguments regarding the rejection of 1-6, 8, 10-13, 17-33 and 43-70, provisionally rejected under the judicially created doctrine of Obviousness Double Patenting over claims 1-15 and 17-20 in copending Application No. 09/942,087, assert that the after final amendment filed on August 21, 2003 at page 10 assert that the copending claims of US Application 09/942,087 are not obvious over the instant claimed subject matter. It is asserted that the claims of 09/942,087 are drawn to a method of

regulating gene expression, and that the instant claims are drawn to a method for altering chromatin structure.

The argument is based upon the language submitted in the instant after final amendment which has not been entered, and is therefore moot.

The argument is also based upon the assertion that the instant claims are not drawn to a method of regulating gene expression. Instant claim 12 states, "wherein chromatin modification facilitates activation of a gene of interest." This is regulation of gene expression. Claim 12 depends from claim 1, and independent claim 1 must embrace all limitations. Therefore, the argument is not persuasive.

Arguments regarding the rejection of claims 1-6, 8, 10-13, 17-33 and 43-70, rejected under 35 USC 112, first paragraph, written description, assert that the after final amendment filed on August 21, 2003 at page 10 assert that the term "component" is defined in the specification, and cites page 24, lines 19-21, "[a] component of a chromatin remodeling complex can comprise **one of its constituent proteins** or a functional fragment thereof". It is also asserted that the Examples 6-10 describe methods of use of a "component".

This citation describes that the chromatin remodeling complex can comprise (emphasis added) one of its constituent proteins. Rather than defining the word component, this phrase merely suggests that the component may (emphasis added) be a constituent protein. The cited section neither defines, nor limits what the "component"

may be. The Examples cited do not provide a definition for the term "component". Therefore, the argument is not found persuasive.

Arguments presented in the after final amendment filed on August 21, 2003 at page 11 traverse the rejection of claims 1-6, 8, 10-13, 17-33 and 43-70 under 35 USC 112, second paragraph. It is asserted that the term "component" is an art recognized term which refers to a polypeptide present in a multiprotein chromatin complex.

Applicants' specification does not limit the term "component" to a polypeptide. Therefore, the argument is not found persuasive.

Arguments presented in the after final amendment filed on August 21, 2003 at pages 11-12 assert that the rejection of claims 1-5, 8, 10, 17, 18 and 68-70 under 35 USC 102(e) over Verdine et al. does not anticipate the instant claims. It is asserted that Verdine et al. teach a transcriptional modulator, and do not teach a chromatin remodeling complex. It is further asserted that Verdine et al. recites that the DNA binding domain is not fused to a chromatin remodeling protein, necessitating a ligand binding element to bridge to a second molecule comprising the chromatin remodeling protein.

Verdine et al. teach at column 21, lines 27-28 "a transcriptional modulator that regulates gene expression by altering the chromatin structure". Thus, the transcriptional modulator is a part of a chromatin remodeling complex. Verdine et al. teach at column 22, lines 3-5 "the chimeric protein preferably includes at least one DNA-binding domain,

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a ligand-binding domain and a transcription modulating domain". Thus, the DNA-binding domain and the transcriptional modulator are comprised in a single fusion protein. Therefore, the arguments are not found persuasive.

Arguments presented in the after final amendment filed on August 21, 2003 at pages 11-13 assert that the rejection of claims 1-6, 8, 10-13, 17-33 and 43-70 under 35 USC 103 over Verdine et al. in view of Peterson et al. and further in view of Cardoso et al. and Omichinski et al. do not make the instant claims obvious. It is asserted that Verdine et al. teach a transcriptional modulator, and does not teach a chromatin remodeling complex. It is further asserted that Verdine et al. requires that the DNA binding domain is not fused to a chromatin remodeling protein, necessitating a ligand binding to a second molecule comprising the chromatin remodeling protein. It is asserted that Peterson et al. is directed to assays and reagents for chromatin remodeling enzymes, and is entirely silent as to DNA binding molecules. It is further asserted that Cardoso et al. and Omichinski et al. do not teach altering the structure of chromatin, and Rutter et al. teaches a single nucleotide polymorphism in a gene, and does not suggest the instant claimed methods.

Verdine et al. teach at column 21, lines 27-28 recite "a transcriptional modulator that regulates gene expression by altering the chromatin structure". The transcriptional modulator is the chromatin remodeling complex. Verdine et al. teach at column 22, lines 3-5 "the chimeric protein preferably includes at least one DNA-binding domain, a ligand-binding domain and a transcription modulating domain". The chimeric protein

comprises a DNA binding domain and a transcriptional modulating domain (chromatin remodeling complex). Therefore, the arguments are not found persuasive.

Peterson et al. is relied upon to teach that a chromatin remodeling complex can render a gene accessible to a second molecule which modulates the expression of a gene. Peterson et al. discusses at column 10, lines 39-60 the usefulness of chromatin remodeling to provide access to DNA binding molecules such the estrogen receptor molecule and the glucocorticoid receptor for regulating transcription (gene activation/repression).

Cardoso et al. recite at the abstract "[t]o investigate whether XNP could mediate activity of gene-specific activators through chromatin remodeling, we performed a yeast two-hybrid analysis using XNP and several human heterochromatin-associated proteins". Thus, Cardoso et al. teach altering chromatin structure. Cardoso et al. teach the binding of a zinc-finger protein fused to a polypeptide from a chromatin remodeling complex. The fusion protein is used in a method of activating gene expression. Cardoso et al. discuss the importance of chromatin remodeling in the method.

Omichinski et al. teach at page 130 a discussion of how to use a zinc-finger fusion protein and remodeling heterochromatin structure for gene activation/repression, including major and minor groove binding.

Rutter et al. teach at the introduction, the importance of a single nucleotide polymorphism in a gene of interest, and discuss the importance of access of transcription factors to the gene for control of transcription of a gene with a single nucleotide polymorphism. Rutter et al. discuss effect of a single nucleotide

polymorphism on a DNA binding protein and on transcription of a gene. This discussion imputes the importance of chromatin remodeling for access to a gene as described by all of the above references.

For all of the above reasons, the arguments are not found convincing.

Arguments presented in the after final amendment filed on August 21, 2003 at page 13 assert that the rejection of claims 1-6, 8, 10-13, 17-33 and 43-70 under 35 USC 103 over Verdine et al. in view of Peterson et al. and further in view of Cardoso et al. and Omichinski et al. lacks motivation to combine the cited references.

Without further arguments as to any specifics, the motivation presented in the rejections of claims 1-6, 8, 10-13, 17-33 and 43-70 under 35 USC 103 over Verdine et al. in view of Peterson et al. and further in view of Cardoso et al. and Omichinski et al. is clear and concise, and does not need further comment. The argument is not found persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Sandals whose telephone number is (703) 305-1982. The examiner can normally be reached on Monday through Thursday between 7:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

William Sandals


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